

### **REMARKS/ARGUMENTS**

The foregoing amendments to the claims are of a formal nature, and do not add new matter. Claims 119-138 were pending in this application and were rejected on various grounds. Claims 119-122, 127-128 and 132-134 are canceled without prejudice or disclaimer. Claim 123 has been amended to recite "wherein the polypeptide encoded by said nucleic acid induces chondrocyte redifferentiation." Claims have also been amended to delete references to Figures and "the extracellular domain". The rejections to the presently pending claims are respectfully traversed.

### **Priority**

Applicants submit that they rely on the chondrocyte redifferentiation assay (Example 159) for patentable utility for this application. As the Examiner has rightly pointed, this data was first disclosed in the International Application No. PCT/US00/08439, filed March 30, 2000, the priority of which is claimed in the present application. Hence, Applicants are entitled to at least an effective filing date of **March 30, 2000**.

### **Title**

The title of the invention has been amended to better describe the claimed invention.

### **Claim Rejections – 35 U.S.C. §112, Second Paragraph**

A. Claims 119-138 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite.

The Examiner asserts that the protein identified as PRO1184 is disclosed as a soluble protein and accordingly, claims that recite an "extracellular domain" is indefinite as the art does not recognize soluble proteins as having such domains.

Without acquiescing to the propriety of this rejection, merely to expedite prosecution in this case, Applicants have deleted any reference to "extracellular domains" in the pending claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

B. Claims 133 was rejected as vague and indefinite for reciting the term "hybridizes" without reciting any conditions or reciting "stringent conditions" wherein these conditions are not known.

In view of the cancellation of Claim 133, Applicants respectfully request that this rejection be withdrawn.

**Claim Rejections – 35 U.S.C. §112, First Paragraph - Enablement**

Claims 119-124, 127, 128 and 132-138 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserts that while the specification enables the nucleic acids that encode the polypeptide defined by SEQ ID NO: 269, it does not enable other variants which do not have a functional activity. The Examiner notes that the claims are broad because they do not recite any functional activity and hence, asserts that it would require undue experimentation to use the invention commensurate in scope with the claims.

The instantly pending claims have been amended to include a functional recitation "wherein the polypeptide encoded by said nucleic acid induces chondrocyte redifferentiation" Applicants have further removed references to "extracellular domains". Accordingly, Applicants submit that the skilled artisan would not require undue experimentation to make and use the claimed invention.

Accordingly, Applicants request that this rejection be withdrawn.

**Claim Rejections - 35 U.S.C. §112, First Paragraph - Written Description**

Claims 119-124, 127, 128 and 132-138 are rejected under 35 U.S.C. 112, first paragraph, for not describing the subject matter in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing".

Without acquiescing to the propriety of this rejection, Applicants have amended Claim 123 to recite a functional recitation: "wherein the polypeptide encoded by said nucleic acid induces chondrocyte redifferentiation." Claims 119-122, 127-128 and 132-134 have been canceled without prejudice or disclaimer and hence this rejection is moot with respect to these claims. Applicants respectfully traverse this rejection to the remaining pending claims.

### **The Legal Standard for Written Description**

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph, is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." In re Kaslow, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. See *e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. Union Oil v. Atlantic Richfield Co., 208 F. 3d 989, 996 (Fed. Cir. 2000).

### **Arguments**

As noted above, whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. The instant invention, defined by the claims, concerns nucleic acids encoding polypeptides having 80%, 85%, 90%, 95% or 99% sequence identity with the disclosed nucleic acid sequence of SEQ ID NO: 269 and further, with the functional recitation: "wherein the polypeptide encoded by said nucleic acid induces chondrocyte redifferentiation." Based on the detailed description of the cloning and expression of variants of PRO1184 in the specification, the description of the chondrocyte redifferentiation assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequence

SEQ ID NO: 269 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know that Applicants possessed the invention as claimed in the instant claims.

Hence, Applicants submit that this rejection should be withdrawn.

**Claim Rejections - 35 U.S.C. §102 and §103**

Claims 119-122 and 132-137 were rejected under 35 U.S.C. §102(b) as being anticipated by Birren *et al.* (March 26, 2000).

Claims 132-134 were rejected under 35 U.S.C. §102(b) as being anticipated by Hillier (1996).

Claim 138 was rejected under 35 U.S.C. §103(a) as being unpatentable over Birren as applied to Claims 119-122 and 132-137 and in view of Sibson.

In view of the cancellation of Claims 119-122, 132-134 and the change in claim dependency of Claim 138 indirectly to Claim 124, Birren does not anticipate or render obvious Claim 138. Accordingly, Applicants submit that these rejections should be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641, referencing Attorney's Docket No. 39780-2730 P1C57).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

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